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Proposed Registration Decision PRD2013-02

Ammonia (Present as Ammonium Sulfate)

(publié aussi en français)

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Overview

Proposed Registration Decision for Ammonia present as Ammonium Sulfate

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of the technical product Fennosurf 583-T and the end-use product Fennosurf 583-C, containing the technical grade active ingredient ammonia (present as ammonium sulfate), to control bacteria and fungi in pulp and paper mills.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Fennosurf 583-T and Fennosurf 583-C.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

Before making a final registration decision on ammonia (present as ammonium sulfate), the PMRA will consider all comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on ammonia present as ammonium sulfate, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is Ammonia (present as Ammonium Sulfate)?

Ammonia (present as ammonium sulfate) is the active ingredient in the end-use product Fennosurf 583-C which is proposed to control bacteria and fungi in pulp and paper mills.

Ammonium sulfate provides a source of ammonia (NH_3). The active ingredient of the Fennosurf 583-C treatment is monochloramine (NH_2Cl), which is being generated *in situ* when the ammonia from the ammonium sulfate reacts with the sodium hypochlorite. This reaction occurs through a dispensing device mixing sodium hypochlorite and Fennosurf 583-C. Monochloramine is known to kill cells by destroying and/or impairing cell walls as well as inhibiting proteins.

Health Considerations

Can Approved Uses of Ammonia (present as Ammonium Sulfate) Affect Human Health?

Ammonia (present as Ammonium Sulfate) is unlikely to affect human health when it is used according to label directions.

Exposure to ammonia (present as ammonium sulfate) may occur when handling the end-use product, Fennosurf 583-C (7.73% ammonia present as ammonium sulfate), which has a proposed commercial use as an antimicrobial product intended for pulp and paper mills. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

The technical grade active ingredient, Fennosurf 583-T (25.5 % ammonia present as ammonium sulfate), is considered to be of low acute toxicity via the oral, dermal and inhalation routes of exposure. It is slightly irritating to eyes and skin, and is not expected to be a dermal sensitizer. Precautionary statements alerting users to the potential for eye and skin irritation are required on both the technical grade active ingredient and end-use product labels.

Dermal or inhalation exposure is possible for workers performing loading, clean-up and repair activities involving the end-use product, Fennosurf 583-C, and for workers engaged in postapplication activities such as coupling or uncoupling transfer lines. Accidental exposure to the eyes may occur if the product is splashed during handling. Therefore, precautionary measures including personal protective equipment are required on the end-use product label to mitigate such exposure concerns. The potential for bystander exposure is expected to be minimal as non-workers are not expected to be present in the wastewater treatment plant, and the end-use product is to be used in a closed system.

Residues in Water and Food

The proposed use of Fennosurf 583-C is for treatment of process waters in the production of non-food contact paper. Dietary intake is not anticipated.

No risk due to exposure from drinking water is anticipated.

Occupational Risks From Handling Fennosurf 583-C

Occupational risks are not of concern when Fennosurf 583-C is used according to label directions, which include protective measures.

Occupational exposure to individuals handling Fennosurf 583-C is not expected to result in unacceptable risk when the product is used according to label directions.

Precautionary (for example, wearing of personal protective equipment) and hygiene statements on the label aimed at mitigating exposure are considered adequate to protect individuals from any unnecessary risk due to occupational exposure.

Environmental Considerations

What Happens When Ammonia (present as Ammonium Sulfate) Is Introduced Into the Environment?

Ammonia (present as ammonium sulfate) is to be used in pulp and paper mills process water systems for the control of bacteria and fungi. The product is applied in conjunction with sodium hypochlorite to form monochloramine, a slow-acting oxidizing microbicide. Monochloramine, which is the primary chemical of environmental concern with the use of Fennosurf 583-C, could potentially enter the environment through industrial effluent discharge. Discharges can be to both freshwater and marine water bodies, as industrial facilities where this product is to be used can

be located near both types of aquatic environments. Due to biological degradation during effluent treatment processes, and through chemical activity within the treatment system, levels of monochloramine discharged to the environment through effluent are expected to be very low. However, the chemical is toxic to aquatic organisms, and label statements requiring dechlorination of effluent to undetectable concentrations will be required prior to discharge, where applicable.

Value Considerations

What Is the Value of Fennosurf 583-C?

Fennosurf 583-C is used for the control of bacteria and fungi growth in pulp and paper mills.

In pulp and paper mills, the microorganisms such as bacteria and fungi must be controlled. These organisms can produce biofilms (slimes) on process equipment. Biofilms can also produce hydrogen sulfide, which is corrosive to machinery. Sloughing off of the biofilms leads to defects in the final paper sheet and disruptions of the paper making process. This results in a lower efficiency in the paper making process. In addition, bacteria and fungi growth can lead to spoilage of pulp resulting in significant waste and economical losses. Fennosurf 583-C will provide a source of ammonia to be mixed with sodium hypochlorite to generate monochloramine. This new active ingredient provides an alternative for the treatment of free floating bacteria and fungi in fouled paper systems.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Fennosurf 583-C to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

The statements 'May irritate eyes and skin', 'Avoid contact with skin, eyes and clothing', 'Avoid breathing vapour or spray mist' are required on the secondary display panel of the technical grade active ingredient end-use product labels.

The personal protective equipment for all loading, cleanup and repair activities required on the end-use product label includes protective eyewear, coveralls or long pants and long sleeved shirt, chemical resistant gloves, socks and chemical resistant footwear.

Environment

Label statements necessitating dechlorination of effluent to non-detectable concentrations when monochloramine residuals (measured as total chlorine, Cl_2) are detected prior to discharge are required.

A label statement indicating toxicity to aquatic organisms is required.

Next Steps

Before making a final registration decision on ammonia (present ammonium sulfate), the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

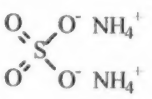
When the PMRA makes its registration decision, it will publish a Registration Decision on ammonia (present as ammonium sulfate) (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Ammonia (present as Ammonium Sulfate)

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Ammonium sulfate
Function	Slimicide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	Diammonium sulfate
2. Chemical Abstracts Service (CAS)	Ammonium sulfate
CAS number	7783-20-2
Molecular formula	$(NH_4)_2SO_4$
Molecular weight	132.14
Structural formula	
Purity of the active ingredient	25.5% Ammonia (present as ammonium sulfate)

1.2 Physical and Chemical Properties of the Active Ingredient and End-Use Product

Technical Product—Fennosurf 583-T

Property	Result
Colour and physical state	White crystalline solid
Odour	No odour
Melting range	235-280°C
Boiling point or range	Not applicable
Density	1.769 g/cm^3
Vapour pressure at 20°C	Not applicable

Ultraviolet (UV)-visible spectrum	Not applicable
Solubility in water at 20°C	1 g/1.5 mL
Solubility in organic solvents at 20°C (g/100 mL)	Insoluble in alcohol
n-Octanol-water partition coefficient (K_{ow})	$K_{ow} = 3.16 \times 10^4$ (calculated)
Dissociation constant (pK_a)	9.21 ammonium ion (base ammonia) -3 sulfuric acid (base HSO_4^-) 1.92 hydrogensulfate (base sulfate)
Stability (temperature, metal)	Stable at normal temperature; incompatible with strong oxidizers, ammonium nitrate and potassium or sodium potassium alloy, and potassium chlorate.

End-Use Product—Fennosurf 583-C

Property	Result
Colour	Colourless
Odour	Slight ammonia odour
Physical state	Liquid
Formulation type	Solution
Guarantee	7.73% ammonia (present as ammonium sulfate)
Container material and description	IBC-polyethylene bottle in steel frame, 1000 - 19208 L
Density	1.12-1.22 g/mL
pH of 1% dispersion in water	6.5
Oxidizing or reducing action	Avoid contact with strong oxidizing agents
Storage stability	Expected to be stable at ambient conditions
Corrosion characteristics	Expected to be non-corrosive to the packaging material; non-corrosive to metals
Explodability	Not applicable

1.3 Directions for Use

Fennosurf 583-C is proposed for control of bacteria and fungi in pulp and paper mills.

The mixing is to be done at a ratio of 2.09–3.14 litres of Sodium Hypochlorite with 1 litre of Fennosurf 583-C. Add sufficient biocide to achieve and maintain a measured concentration of 0.5–3.0 ppm residual biocide, expressed as total chlorine. When the system is noticeably fouled, it may be necessary to slug feed to a concentration up to 7 ppm expressed as total chlorine to obtain desired control.

1.4 Mode of Action

The ammonia (present as ammonium sulfate) in Fennosurf 583-C provides a source of ammonia to be mixed with sodium hypochlorite through a dispensing device. Ammonia and ammonium compounds will react *in situ* with sodium hypochlorite to form chloramines. The reaction is closely controlled in the device in terms of pH to form only monochloramine, which is known to kill cells by destroying and/or impairing cell walls as well as inhibiting proteins.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the active ingredient and the impurities in ammonia (present as ammonium sulfate) technical product are the methods outlined in the Food Chemicals Codex and therefore acceptable.

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulation is the method outlined in the Food Chemicals Codex and therefore acceptable for use as an enforcement analytical method.

2.3 Methods for Residue Analysis

The active ingredient and the major transformation products are simply ammonia/ammonium ion, nitrogen, nitrate ion, chloride ion and chloramine which can be analyzed using well-established methods such as those found in *Standard Methods for the Examination of Water and Wastewater*; these methods are acceptable for enforcement purposes without validation.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A detailed review of the toxicological database for the active ingredient ammonia (present as ammonium sulfate) consisting of waiver rationales was conducted. The scientific quality of the data is acceptable and the database is sufficiently complete to define the majority of the toxic effects that may result from exposure resulting from the proposed use of this pest control product.

The acute toxicity of ammonia and ammonium sulfate has been well characterized in publicly available scientific literature. Available information suggests that the active ingredient is of low acute toxicity by the oral, dermal, and inhalation routes of exposure. Ammonia (present as ammonium sulfate) is minimally irritating to the skin, slightly irritating to the eyes, and is not considered a dermal sensitizer.

Based on information for short-term toxicity, prenatal developmental toxicity, genotoxicity, and chronic toxicity available for ammonia (present as ammonium sulfate) at the time of evaluation, coupled with a long history of safe use as a household cleaning agent, it appears unlikely that treatment-related effects will result from exposure to ammonia (present as ammonium sulfate).

3.1.1 Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the Health Canada website. Incidents from Canada were searched and reviewed for the active ingredient ammonia (present as ammonium sulfate). As of 11 October 2012, there have been no human incident reports for products containing ammonia (present as ammonium sulfate) in Canada.

3.2 Food Residue Exposure Assessment

The slimicide, monochloramine, which results when combining Fennosurf 583-C with sodium hypochlorite, is used in the process of treating paperboard products which are intended for non-food uses. Dietary exposure to monochloramine or any unreacted Fennosurf 583-C is not expected. Likewise, no risk due to exposure from drinking water is anticipated.

3.3 Occupational and Residential Risk Assessment

3.3.1 Use Description / Exposure Scenario

The proposed commercial use for Fennosurf 583-C is to control bacteria and fungi in pulp and paper mills. Fennosurf 583-C is to be delivered in a sealed intermediate bulk container (IBC), which will be opened and connected to the Kemira Feeder System with a feeder hose by a trained technician. This is an enclosed process with no anticipated exposure to the operator

except when the IBC is hooked up to the feeder system and during removal of the spent container. Fennosurf 583-C is mixed with sodium hypochlorite at the rate of 1 L of Fennosurf 583-C to 2.09–3.14 L of sodium hypochlorite. The mixture is then dispensed into the industrial process waters such that a measured concentration of 0.5–3.0 ppm residual biocide expressed as total chlorine is maintained. It is anticipated that a new container will be required every four days. When the system is noticeably fouled, it may be necessary to slug feed to a concentration of up to 7.0 ppm expressed as total chlorine to obtain desired control.

3.3.2 Occupational Exposure Risk Assessment

Occupational exposure to Fennosurf 583-C may occur during loading, clean-up and repair. The predominant route of exposure would be dermal during these activities, although exposure by the inhalation route would also be possible. Accidental exposure to the eyes may occur if the product is splashed during handling. Personal protective equipment requirements on the end-use product label instruct workers to wear protective eyewear (goggles or face shield), long pants, long sleeved shirt, chemical resistant footwear and chemical resistant gloves when handling the product and contacting treated process fluids. Additional precautionary and hygiene statements instruct workers to avoid contact with skin, eyes and clothing, to avoid breathing the vapour or spray mist, to wash thoroughly with soap and water after handling, and to remove contaminated clothing and wash before reuse. Exposure of workers to Fennosurf 583-C will be appropriately mitigated through the requirements for personal protective equipment, observing precautionary and hygiene statements, and the nature of the closed system where the end-use product will be used. Therefore, occupational exposure to Fennosurf 583-C is expected to be minimal when workers follow the label directions.

3.3.3 Bystander Exposure Risk Assessment

As Fennosurf 583-C is to be used in a closed system in a pulp and paper mills where bystanders are not expected to be present, no bystander exposure to the end-use product is expected to occur.

3.3.4 Postappplication Exposure

There is a potential for worker exposure to Fennosurf 583-C during postapplication activities such as coupling or uncoupling transfer lines. However, postapplication exposure to Fennosurf 583-C is expected to be minimal when workers follow the required personal protective equipment and precautionary and hygiene statements on the product label.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Ammonia (present as ammonium sulphate) is mixed with sodium hypochlorite to form monochloramine, a relatively slow-acting oxidizing microbicide. Once formed, monochloramine will readily transform into multiple compounds (other inorganic chloramines, organic

chloramines, ammonia, and free chlorine). This closely related group of reaction products is collectively referred to as monochloramine residuals, which are typically measured in terms of mg Cl_2/L (total chlorine). The fate of monochloramine residuals once discharged into the environment is influenced by water-phase processes, including dilution, mixing, advection, chemical demand, benthic demand, photodegradation, volatilization, sediment adsorption and reaction, and sediment associated transport, deposition, burial and resuspension. Considering all processes, available data suggest that monochoramines have a half-life of 2 to 41 days. As such, monochloramine residuals can be categorized as non-persistent to slightly persistent in aquatic systems.

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations to which adverse effects occur. Estimated environmental concentrations are concentrations of pesticide in various environmental media, such as food, water, soil and air. The estimated environmental concentrations are estimated using standard models which may take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints.

Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicology endpoints in risk assessments may be adjusted by applying an uncertainty factor to account for potential differences in species sensitivity as well as varying protection goals (as in protection at the community, population, or individual level). A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern. If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios. If the generation of quantitative data is not practical for a particular active ingredient/product, a qualitative assessment may be more appropriate.

The risk assessment for ammonia present as ammonium sulfate is quantitative (screening level risk assessment) and qualitative (refined risk assessment).

4.2.1 Risk to Terrestrial Organisms

Limited risk to non-target terrestrial species is expected from the use of ammonia (present as ammonium sulfate) and any resulting monochloramine input into the environment. The proposed use pattern of this product would not result in terrestrial exposure.

4.2.2 Risk to Aquatic Organisms

The toxicity of monochloramine resulting from the use of ammonia (present as ammonium sulfate) to aquatic organisms as well as the screening level RQs are presented in Appendix 1, Table 2.

Non-target aquatic organisms may be exposed to monochloramine residues through effluent discharge from pulp and paper mills, as these industries are typically located near aquatic environments (freshwater and marine). Through activity within the treatment system, and through biological degradation during secondary treatment, the amount of monochloramine discharged into the aquatic environment through the use of ammonia present as ammonium sulfate is expected to be below the level of detection, measured as total chlorine. The level of detection for total chlorine is typically 0.01 or 0.02 mg/L, depending on the analytical method that is used. The higher value, 0.02 mg/L was chosen as the estimated environmental concentration for this review because this is the more conservative value of the two.

Even at very low concentrations, monochloramine residuals can be toxic to aquatic organisms. A screening level risk assessment, comparing toxicity values for groups of aquatic organisms to a concentration of 0.02 mg total chlorine/L in undiluted effluent, indicated some risk to non-target aquatic organisms with RQs ranging from 2.2 to a maximum of 5. It is unlikely that residues would present significant acute or chronic risk to aquatic organisms given the following: RQ values are relatively low indicating that the risk is likely to be low; the screening level risk assessment did not consider dilution in the receiving water, which is expected to be rapid; and monochloramine levels discharged to the environment are expected to be low and are likely to be subjected to further degradation. As a precaution to further mitigate the risk to aquatic organisms, label statements requiring dechlorination (to non-detectable concentrations, less than 0.01 or 0.02 mg/L) of industrial process water prior to discharge into the environment will be required.

5.0 Value

5.1 Effectiveness Against Pests

Data from three laboratory and confirmatory historical data of operational use from two different pulp and paper mills were provided. Monitoring of various parameters such as monochloramine levels, adenosine triphosphate levels, bacterial and fungal growth were followed over significant periods of time (for example, several months). These laboratory study and operational data demonstrated the capacity of Fennosurf 583-C to control bacteria and fungi in pulp and paper mills in various conditions.

5.1.1 Acceptable Efficacy Claims

The acceptable claim for Fennosurf 583-C is to control bacteria and fungi in pulp and paper mills.

5.2 Economics

No information provided.

5.3 Sustainability

5.3.1 Survey of Alternatives

More than 40 different active ingredients or combinations of active ingredients are registered for use in pulp and paper mills in use-site category 17 (Industrial process fluids) (see Appendix I, Table 3).

5.3.2 Information on the Occurrence or Possible Occurrence of the Development of Resistance

No resistance has been reported and industry generally avoids resistance by using a lower day-to-day treatment rate, and then if organisms proliferate, slug feeding the system with the higher label concentration. In addition to increasing the treatment dosage and changing the treatment program (for example, from continuous to intermittent, using variations on length and intensity of dosing shocks, etc.) it is possible to introduce an alternating treatment program of a different type (for example, alternate a Fennosurf 583-C program with a biocide having a different mode of action).

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e., persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, Fennosurf 583-T, and reaction chemicals including monochloramine, were assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- Fennosurf 583-T does not meet all Track 1 criteria, and is not considered a Track 1 substance. Ammonium sulfate is unstable in water and dissociates rapidly to ammonium and sulfate ions.
- Transformation products of Fennosurf 583-T do not meet the Track 1 criteria. Available data suggest that monochoramines have a half-life of 2 to 41 days in water (non-persistent to slightly persistent).

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*[6]. The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including: DIR99-03 and DIR2006-02[8], and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Technical grade Fennosurf 583-T and the end-use product Fennosurf 583-C do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.[9]

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5 DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

6 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

7 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.*

8 DIR2006-02, *Formulants Policy and Implementation Guidance Document.*

9 DIR2006-02, *Formulants Policy and Implementation Guidance Document.*

7.0 Summary

7.1 Human Health and Safety

The available information for the active ingredient ammonia (present as ammonium sulfate) is adequate to qualitatively identify the toxicological hazards that may result from human exposure to the end-use product, Fennosurf 583-C. Ammonia (present as ammonium sulfate) is considered to be of low acute toxicity by the oral, dermal, and inhalation routes of exposure. It is minimally irritating to the skin, slightly irritating to the eyes, is not considered a dermal sensitizer, and is non-mutagenic.

Occupational exposure to Fennosurf 583-C is expected to be minimal if the precautionary statements and recommended personal protective equipment on the product label, which are intended to minimize worker exposure, are observed. Bystander exposure is likely to be negligible. Postapplication exposure can be minimized by following the precautionary statements on the label.

7.2 Environmental Risk

A potential risk to fresh water and marine organisms from the use of ammonia (present as ammonium sulfate) due to the formation of monochloramine could occur if concentrations in discharge effluent significantly exceed 0.02 mg/L. To minimize potential toxic levels of monochloramine residuals present in effluent discharged to the environment, a label statement directing facilities to conduct dechlorination of process water when detectable concentrations of total chlorines are measured will be required. Standard environmental label statements for products than can be released into aquatic environment will also apply. With these mitigative measures, this product is expected to pose a minimal risk to non-target organisms.

The chemicals of concern, monochloramine and residuals, are not expected to build-up in the environment under the current use pattern, and exposure to non-target organisms is expected to be low. Risk to the environment through this use is expected to be minimal.

7.3 Value

The data submitted in support of Fennosurf 583-C was adequate to demonstrate its efficacy for use against bacteria and fungi which can form biofilms. Fennosurf 583-C has a specific mode of action which will provide an alternative for the treatment of fouled systems. Since biofilms that form on process equipment can lead to corrosion of the machinery, to defects in the final paper sheet, and ultimately to disruptions of the paper making process, this product will help to reduce the waste of pulp and paper and the associated economic losses.

7.4 Unsupported Uses

The use of Fennosurf 583-C against algae could not be supported with the data provided. This use was withdrawn at the request of the applicant.

8.0 Proposed Regulatory Decision

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Fennosurf 583-T and Fennosurf 583-C, containing the technical grade active ingredient Ammonia present as Ammonium Sulfate, to control bacteria and fungi in pulp and paper mills.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

EEC	estimated environmental concentration
IBC	intermediate bulk container
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
MCA	monochloramine
mL	millilitre
NH_3	ammonia
NH_2Cl	monochloramine
PMRA	Pest Management Regulatory Agency
ppm	parts per million

Appendix I Tables and Figures

Table 1 Summary of Acute Toxicity, Irritative Effects, and Sensitization Information for Ammonium Sulfate

Study	Species/Strain and Doses	Result	Target Organ / Significant Effects / Comments
Acute oral toxicity studies Exposure by gavage	Rat and mouse	LD_{50} (rats) > 4250 mg/kg bw LD_{50} (mice) > 2000 mg/kg bw **Low acute toxicity.**	No mortality occurred.
Acute dermal toxicity study	Rat and mouse	LD_{50} > 2000 mg/kg bw **Low acute toxicity.**	No mortality occurred.
Acute inhalation toxicity studies	Rat	LC_{50} (♀) > 2.39 mg/L LC_{50} (♂) > 2.39 mg/L **Low acute toxicity.**	No mortality occurred.
Eye Irritation Draize method	Rabbit – New Zealand White Dose: 50 mm^3 of neat ammonium sulfate.	**Slightly irritating.**	Slight edema and conjunctival redness was noted one hour after instillation. Slight redness present at 24 h.
Dermal Irritation Draize method	Rabbit – New Zealand White	**Minimally irritating.**	Prolonged contact with skin may result in irritation. Symptoms may include redness, itching, and pain.

Study	Species/Strain and Doses	Result	Target Organ / Significant Effects / Comments
Dermal Sensitization	n/av	Long history of use involving dermal contact (*for example*, fertilizers, household cleaners) suggests that ammonium sulfate is not a dermal sensitizer.	n/a

Table 2 Screening Level Risk Assessment (Ra) for Inorganic Chloramine for Non-Target Aquatic Organisms

Organism	Toxicity value	RA endpoint = Toxicity value / Uncertainty factor	EEC*	RQ
Freshwater invertabrate *Ceriodaphnia dubia*	Incipient LC_{50} = 0.018 mg/L	0.018/2 = 0.009 mg/L	0.02 mg/L	**2.2**
Marine invertebrate (freshwater invertebrate *C. dubia* toxicity endpoint surrogate)	Incipient LC_{50} = 0.018 mg/L	0.018/2 = 0.009 mg/L	0.02 mg/L	**2.2**
Freshwater fish Chinook salmon	Incipient LC_{50} = 0.09 mg/L	0.09/10 = 0.009 mg/L	0.02 mg/L	**2.2**
Marine fish (*Menidia menidia)*	96 hr LC_{50} = 0.04 mg/L	0.04/10 = 0.004 mg/L	0.02 mg/L	**5**
Marine Alga -(*Porphyra yezoensis)*	10 day EC_{50} (growth) = 0.014 mg/L	0.014/2 = 0.007 mg/L	0.02 mg/L	**2.9**

* EEC = estimated environmental concentrations

Table 3 Alternative Products

More than 40 alternatives exist for this type of use. The following is a table of some example of these alternatives.

Type of active ingredient	Pest Control Product # of examples of end-use products with this active ingredient
Alkyl Trimethylenediamines	19863
Hydantoins	26986
Isothiazolones	25660
Bronopol	21790
Quaternary ammonium compounds	25503
Glutaraldehyde	28686
Oxidizers	26166, 25258, 30179
Carbamates	18619

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

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2057187 2011, DACO 2.11.2 & 2.11.3 from GAC, DACO: 2.11,2.11.2,2.11.3 CBI

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2.0 Human and Animal Health

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2057262 Exposure Summary, DACO 5.1.

2057263 Use Description/Scenario (Application and Post Application), DACO 5.2.

3.0 Environment

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4.0 Value

2138362	10.2.3.2	Efficacy of monochloramine (MCA) on fungi
2138364	10.2.3.3	Effect of high threshold dosage of MCA on Broke quality recovery
2078451	10.2.1	Mode of action
2078453	10.2.2	Description of Pest Problem
2057256	10.2.3.4	Field Efficacy Study (Alabama)
2057254	10.2.3.2	Comparison of the biocidal efficacy of sodium hypochlorite alone to the efficacy of sodium hypochlorite together with Fennosurf 583
2085471		Correspondence
2088102		Correspondence and field trial

B. Additional Information Considered

i) Published Information

1.0 Human and Animal Health

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2057194 Canada Food and Drug Regulations, Section B.16.100, Table XIV Food additives that may be used as yeast foods.

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